August 25, 2000

Mr. James H. Carlson, Acting Director
Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT REPORT NO. OAR- 00-07, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-010"

Dear Mr. Carlson:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-07 of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD), audit of activities pertaining to the Saturated Zone Flow and Transport Process Model Report (SZ PMR) performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-010, was conducted on June 21-30, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this performance based audit was to evaluate the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for the SZ PMR and selected Analysis Model Reports (AMRs) supporting the SZ PMR.

The NRC staff determined that this audit was effective in identifying potential weaknesses and recommending improvements in the PMR/AMR process. During the conduct of the audit, both the audit team and the NRC observers independently reviewed applicable data, analysis reports, and software to confirm that it was properly qualified. As a result of these activities the NRC observers determined that the M&O had made substantial progress with respect to the qualification and verification of data and software which support the PMRs/AMRs. However, because of the importance of these activities which will sustain site recommendation and the potential license application, the staff recommends that DOE and the M&O maintain their emphasis on the timely qualification and verification of data and software which support the technical adequacy of PMRs/AMRs.

The NRC staff generally agreed with the audit team conclusions, findings, and recommendations as presented at the Post-audit Conference. Within the areas evaluated, no deficiencies were identified and the NRC observers concluded that the technical quality and completeness of the scientific products contained in the SZ PMR and the associated AMRs indicated an improving trend over the previous six PMR audits performed during the last quarter of 1999 and the first quarter of 2000.

As discussed in Section 4.6 of the attached report, the NRC observers identified three concerns pertaining to the clarification of “issue statements” in Appendix A of the SZ PMR, consideration of alternative conceptual models for the Saturated Zone Flow and Transport Model, and updating of the status of the regional Saturated Zone Flow Model. These concerns which complemented the audit team’s findings will be addressed in DOE’s report of the OCRWM QA Audit M&O-ARP-00-10.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Robert M. Latta of my staff at (702) 794-5048.

Sincerely,

/s/

N. King Stablein, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-07, “Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-010"

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As discussed in Section 4.6 of the attached report, the NRC observers identified three concerns pertaining to the clarification of "issue statements" in Appendix A of the SZ PMR, consideration of alternative conceptual models for the Saturated Zone Flow and Transport Model, and updating of the status of the regional Saturated Zone Flow Model. These concerns which complemented the audit team's findings will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Robert M. Latta of my staff at (702) 794-5048.

Sincerely,

/s/

N King Stablein,(Acting) Chief,
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-07, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-010"

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-07

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-010


/s/ 08/25/00

Robert M. Latta
High-Level Waste Branch
Division of Waste Management

/s/ 08/ 25 /00

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Reviewed and Approved by:


/s/ 08/25/00

N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

## 1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and a contractor from the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed all aspects of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) audit of activities pertaining to the Saturated Zone Flow and Transport Process Model Report (SZ PMR) performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-010, was conducted on June 21–30, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 9, by evaluating the SZ PMR and selected Analysis Model Reports (AMRs) supporting the SZ PMR. During the audit, selected AMRs were subjected to a technical evaluation as well as evaluation to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA are properly implementing the provisions contained in the QARD and the requirements contained in Subpart G, Quality Assurance, to Part 60, of Title 10 of the Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting SR are properly qualified; and 2) evaluating the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of SZ PMR/AMR development.

## 2.0 MANAGEMENT SUMMARY

The NRC staff generally agrees with the audit team conclusion's, findings, and recommendations. The NRC staff determined that OQA Audit M&O-ARP-00-010 was well planned and effectively implemented. Audit team members were independent of the activities they audited and were knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. No deficiencies were identified during the audit. However, twelve recommendations were identified as improvements to the SZ PMR/AMRs or as enhancements to the procedures controlling various elements of the modeling reports process.

During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The audit team and the NRC observers determined that elements of the software

supporting the AMRs had been properly qualified. The audit team and the NRC observer's also determined that certain data, categorized as "accepted data," were appropriately controlled and categorized in accordance with the governing procedures.

## 3.0 AUDIT PARTICIPANTS

### 3.1 Nuclear Regulatory Commission Observers

| | | |
|---|---|---|
| Robert Latta | Team Leader | NRC |
| John Bradbury | Technical Specialist | NRC |
| Latif Hamdan | Technical Specialist | NRC |
| Rod Weber | QA Specialist | CNWRA |

### 3.2 OQA Audit Team

| | | |
|---|---|---|
| Lester Wagner | Audit Team Leader | OQA/Quality Assurance Technical Support Services (OQA/QATSS) |
| Robert Hartstern | Auditor | OQA/QATSS |
| Michael Goyda | Auditor | OQA/QATSS |
| Kenneth McFall | Auditor | OQA/QATSS |
| Chet Wright | Auditor | OQA/QATSS |
| Charles Warren | Auditor | OQA/QATSS |
| Keith Kersch | Technical Specialist | SAIC |
| Thomas Doe | Technical Specialist | Management and Technical Services(MTS) |
| Richard Salness | Technical Specialist | MTS |

### 3.3 Nevada State Observer

| | | |
|---|---|---|
| Susan Zimmerman | Administrator of Technical Programs | Nuclear Waste Project Office, Agency for Nuclear Projects, State of Nevada |

## 4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff' observation of this audit was performed in accordance with NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

### 4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes related to the development of the AMRs supporting the SZ PMR. Audit activities included evaluation of selected AMRs, software, and associated data. The audit also included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. The following procedures, and SZ PMR and supporting AMRs were evaluated by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.1Q, “Indoctrination and Training of Personnel,” Revision 0, with Interim Change Notice (ICN) No. 0

b) AP-2.2Q “Establishment and Verification of Required Educational and Experience of Personnel,” Revision 0, with ICN No. 0

c) AP-2.13Q, “Technical Product Development Planning,” Revision 0, with ICN No.3

d) AP-2.14Q, “Review of Technical Products,” Revision 0, with ICN No. 1

e) AP-2.15Q, “Work Package Planning Summaries,” Revision 0, ICN No.1

f) AP-3.4Q, “Level 3 Change Control,” Revision 1, ICN No.3

g) AP-3.10Q, “Analysis and Models,” Revision 2, with ICN No. 2

h) AP-3.11Q, “Technical Reports” Revision 1, with ICN No. 1

i) AP-3.14Q, “Transmittal of Input” Revision 0, with ICN No. 0

j) AP-3.15Q, “Managing Technical Product Inputs,” Revision 1, with ICN No. 1

k) AP-3.17Q, “Impact Reviews,” Revision 0, with ICN No. 0

l) AP-SI.1Q, “Software Management,” Revision 2, with ICN No. 4

m) AP-SIII-1Q, “Scientific Notebooks,” Revision 0, with ICN No. 1

n) AP-SIII.2Q, “Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data,” Revision 0, with ICN No. 2

o) AP-SIII.3Q, “Submittal and Incorporation of Data to the TDMS,” Revision 0, with ICN No. 3

p) AP-SV.1Q, “Control of the Electronic Management of Data,” Revision 0, with ICN No. 1

q) QAP-18.1, “Auditor Qualification,” Revision 6, with ICN No. 0

Process Model Report

a) TDR-NSB-HS-000001, “Saturated Zone Flow and Transport,” Revision 00

Analysis Model Reports

a) ANL-NBS-HS-000033, “Hydrogeologic Framework Model for the Saturated-Zone Site-Scale Flow and Transport Model,” Revision 00E

b) Analysis Model Report, Calibration of the Site-Scale Saturated Zone Flow Model (MDL-NSB-HS-000011, Rev 00F)

c) ANL-NBS-HS-00003, "Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA," Revision 00

### 4.2 Conduct and Timing of the Audit

The audit was performed effectively and the OQA audit team demonstrated a sound knowledge of the applicable M&O and DOE programs and procedures. Audit team members conducted thorough interviews, they challenged responses when appropriate and they effectively employed their detailed audit checklists. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing SZ PMR activities. However, the audit team was limited in their ability to confirm that data supporting the AMRs had been properly qualified because only a small number of the associated data sets had been qualified in accordance with the requirements of Procedure AP-3.15Q.

The DOE audit team and NRC observers caucused at the end of each day. Meetings between the audit team and M&O management (with the NRC observers present) were also held each morning to discuss the current audit status and preliminary findings.

### 4.3 Audit Team Qualification and Independence

The qualifications of the audit team leader and the OQA audit team were reviewed for accuracy and completeness in accordance with the requirements of Procedure QAP 18.1, "Auditor Qualification". The NRC staff review included an examination of the training, education, experience, and annual evaluation records of the audit team members. As a result of these reviews, one item was identified and discussed with the Auditor Certification Coordinator. Specifically, paragraph 5.1.3 b, of Procedure QAP 18.1, states that the Certification Coordinator shall prepare a memorandum to file attesting to the completion of required training for the prospective auditor. However, the records for three of the more experienced auditors did not contain the specified memorandum. The significance of this issue was determined to be minor, in that the requisite training for these individuals had been accomplished and the only discrepancy was that the individual's files had not been updated to reflect this condition. Subsequent to the identification of this issue, the Certification Coordinator agreed to review the qualification records and take the necessary administrative action to address this oversight.

### 4.4 Examination of Quality Assurance Elements

As defined in the audit schedule, the OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of a technical specialist and a QA auditor. The limited scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of the following QA elements.

#### 4.4.1 AP-2.13Q "Technical Product Development Planning"

The auditors reviewed technical development plans and work product planning sheets applicable to the subject AMRs. In addition, the auditors reviewed the methodology for the product

development, including the tracking of unresolved issues [inputs requiring qualification, to be verified (TBV), etc.]. No significant issues were identified within this area of review.

### 4.4.2 AP-SI.1Q "Software Management"

Software controls associated with the SZ PMR/AMRs were discussed during each of the technical interviews. The auditors reviewed qualification documentation and determined that the requirements of the software management procedure had been met. The Calibration of the Site-Scale Saturated Zone Flow Model draft AMR was found to be based on an older version of the Regional Saturated Zone flow model. The audit team recommended that a discussion of the impact on the AMR and justification for use of the model be included in the AMR. The software SZ-CONVOLUTE was found to be called out twice in the Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA AMR. However, no information for this program was included in the reference listing. Accordingly, it was recommended that a reference be included in the next revision and that it indicate where the software can be found.

### 4.4.3 AP-3.15Q "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input, [e.g. qualified, to be verified (TBV)]. The NRC observers examined the TBV status and determined that it included the appropriate statements in accordance with the Analysis/Model Documentation Outline. For the Calibration of the Site-Scale Saturated Zone Flow Model AMR, Rev. 00E, it was noted by the audit team that there are weaknesses in the statements related to TBV input effects on the model. Accordingly, it was recommended that future revisions provide clarification within this area.

### 4.4.4 AP-3.10Q "Analysis and Models"

Procedure AP-3.10Q was used by the audit team to evaluate the activities covered during the audit. By definition, this procedure applies to activities pertaining to the development, documentation, checking, review, approval, and revision of analyses or models, and the calibration, validation, or use of models to support scientific, engineering, or performance-assessment work activities.

Although the audit team generally concluded that the requirements of Procedure AP-3.10Q have been appropriately implemented, one item related to improved documentation was identified. Specifically, the audit team determined that the SZ PMR and the corresponding UZ PMR had been developed in parallel. This parallel development resulted in the use of input flux in the SZ PMR that is based on a 1997 UZ database which was subsequently updated in 1999. Although the revised data were properly used in the development of the UZ PMR they were not incorporated into the SZ PMR. The M&O staff indicated that an analysis was conducted to assess the impact of the new data, and that this analysis indicated that the impact on the SZ PMR was insignificant. However, the audit team noted that there was no documentation of the impact analysis in the SZ PMR.

The NRC technical observers also noted that alternative conceptual models for SZ flow paths and potentiometric heads including the water table were neither identified nor analyzed as

required by Procedure AP-3.10Q (i.e., in Attachment 1, Section 6: Analysis/Model Documentation Outline).

As established during the Post-audit Conference, these issues were analogous to the findings of the audit team, and they will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

### 4.4.5 AP-2.14Q "Review of Technical Products"

The SZ PMR and two of the AMRs evaluated during this audit were subjected to the technical review process defined in Procedure AP-2.14Q. These AP-2.14Q reviews were performed by the M&O's Data/Software Qualification Department which is external to the organizations that prepared the SZ PMR and AMRs. However, ANL-NBS-HS-00003, "Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA" Revision 00, had not undergone the AP-2.14Q review process.

The NRC observers also examined the process controls for the resolution of to-be-verified (TBV) data used as direct input to AMRs and PMRs, implicit to the review of technical products. As described in Procedure AP-3.15Q, the term "TBV", is used to identify information which is preliminary in nature, that needs to be re-evaluated and/or requires confirmation. The procedural controls of AP-3.15Q, which are applicable to the M&O, the National Laboratories and U.S. Geological Survey (USGS) establish the organizational responsibilities and processes required for the acquisition, tracking, and status of the technical product inputs necessary for the development of Yucca Mountain Site characterization project documents. This procedure also describes the necessary actions to resolve TBVs and to-be-determined (TBDs) and the administrative controls to track incomplete reference checks on inputs used in approved technical products.

The NRC observers held discussions with cognizant individuals in the Data/Software Qualification Department and reviewed selected data tracking number (DTN) sets in order to gain insights into the verification methodology to resolve TBVs.

As a result of these discussions and review activities the NRC observers ascertained that approximately 66% of the data supporting the site recommendation and the potential license application had been qualified and that approximately 85% of the data in the Document Input Reference System (DIRS) had been verified. Based on these values the NRC observers determined that the M&O had made substantial progress with respect to the qualification/verification of data and software which support the AMRs/PMRs. However, because of the importance of these activities which will sustain site recommendation and the potential license application, the staff recommends that DOE and the M&O maintain their emphasis on the timely qualification and verification of data and software which support the technical adequacy of the PMRs/AMRs.

## 4.6 Examination of Technical Activities

Technical specialists on the audit team performed detailed checks of the technical adequacy of the subject SZ PMR/AMRs. Technical observers from NRC observed the audit of the these activities.

The technical specialist qualifications (resumes) were reviewed. As a result of these reviews it was determined that appropriate educational backgrounds, training, and experience for these individuals had been documented.

The technical specialists on the audit team evaluated activities and processes supporting the development of the SZ PMR. The technical specialists used a combination of technical questioning and programmatic compliance checks to verify AMR technical adequacy and QA program effectiveness. The technical activities were evaluated using three evaluation criteria pertaining to transparency; traceability; and defensibility.

The audit checklist included items pertaining to the SZ PMR and three supporting AMRs, which were pre-selected by the auditors from a total of 13 AMRs supporting the SZ PMR. In addition to auditing the pre-selected AMRs, the technical specialists and NRC technical observers also examined information and analyses provided in one other draft AMR. This was a draft AMR pertaining to Water-Level Data Analysis for the Saturated Zone Site-Scale Flow and Transport Model (MDL-NSB-HS-000034, Rev C), which provided information that supported the Hydrogeologic Framework Model (HFM) and Calibration of the Site-Scale Model AMR.

Based on these reviews the NRC observers concurred with the DOE audit team that the technical content of the PMR/AMRs satisfied the audit evaluation criteria. However, the NRC technical staff did identify three concerns related to the SZ PMR which are described in sections 4.6.1 through 4.6.4, of this report. These concerns which complemented the audit team's findings will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

### 4.6.1 Process Model Report, Saturated Zone Flow and Transport (TRD-NBS-HS-000001,Rev.00)

A total of 14 items pertinent to the SZ PMR were included in the audit checklist, and evaluated by the auditors. The following technical subjects were addressed: input data for the SZ site-scale model, unit breakthrough curves, unsaturated zone (UZ) mass flux, input to the convolution integral program, overview of the results of the TSPA calculation, uses of UZ expert elicitation on groundwater fluxes, code verification (FEHM, particle tracker), timing on inputs, and QA issues.

The technical specialists, on the audit team, reviewed the pertinent information concerning the above listed items. Based on the results of these reviews the technical specialists were generally satisfied that the SZ PMR met the audit evaluation criteria. The audit team further determined that the SZ PMR and the corresponding UZ PMR were developed in parallel, which resulted in using input flux in the SZ PMR that was based on a 1997 database that had subsequently been updated in 1999. The audit team ascertained that the new data were appropriately used in the development of UZ PMR, but they were not utilized in the SZ PMR. The M&O staff stated that an analysis was conducted to assess the impact of the new data, and that the impact analysis indicated that the effect on the SZ PMR was insignificant. However, the audit team noted that there was no objective evidence of this analysis in the SZ PMR.

The NRC technical observers also noted that numerous comments on the site-scale and regional SZ flow models provided by outside reviewers had not been appropriately addressed in the SZ PMR. Abstractions of reviewer comments on the SZ flow models were provided in the SZ PMR (i.e., comments by the Nuclear Waste Technical Review Board, DOE's Peer Review Panel, and DOE's SZ Expert Elicitation Panel are provided in Appendix A; and NRC staff

comments are provided in Appendix B of the PMR). However, many of the responses to the comment abstractions were unclear or non-responsive, and it appeared that many of the reviewers concerns were neither resolved nor mitigated.

The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

### 4.6.2 Analysis Model Report, Hydrogeologic Framework Model for the Saturated-Zone Site-Scale Flow and Transport Model, (ANL-NBS-HS-000033, Rev 00E)

A total of 23 audit checklist items, pertinent to this AMR were evaluated by the auditors. The following technical subjects were addressed: data storage and control, scientific notebooks, correlation of borehole data and geologic sections, documentation of calculations and methods, description and documentation of hybrid gridding techniques, plans for qualification of input data, process of inputting borehole logs and geologic maps into the Hydrogeologic Framework Model (HFM), use of the Geologic Framework Model in the HFM, information on geologic cross sections incorporated in the HFM, timeliness of input data update and incorporation of updated HFM model in other models, measures for data sufficiency, method of integration of structural data into the HFM, use of input data to create Stratamodel files, stacking number sequences and consistency between different versions of the HFM, process of leveling and digital referencing to map traces, construction steps of the 3-D HFM and documentation of construction steps in procedure and in scientific notebooks, updating of the potentiometric surface in the HFM, and the processes of clipping versus extrapolation where data do not exist.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the technical specialists were generally satisfied that the this AMR met the audit evaluation criteria.

The NRC technical observers noted that the water table, which constitutes the upper boundary for the HFM has a large measure of uncertainty in that it is based on water level measurements in different aquifer units including confined aquifers. Although the AMR acknowledges that there are alternative conceptual models for the "water table", the NRC technical observers were concerned that these alternative conceptual models were neither identified nor analyzed. Examination of another AMR (i.e., Water-Level Data Analysis for the Saturated Zone Site-Scale Flow and Transport Model, S-000034), which was cited by the M&O staff as the source for the water table model, confirmed that alternative conceptual models of the water level were not identified or analyzed.

The DOE audit team acknowledged the NRC technical observer's concern which was complementary to the audit team findings and agreed to address this item in their report of the OCRWM QA Audit M&O-ARP-00-10.

### 4.6.3 Analysis Model Report, Calibration of the Site-Scale Saturated Zone Flow Model (MDL-NSB-HS-000011, Rev 00F)

A total of 17 audit checklist items, pertinent to this AMR, were evaluated by the auditors. The following technical subjects were addressed: completeness of work including references, checking the results of the NETPATH code, proper referencing of software codes, grid

resolution, FEHM boundary condition macro, local recharge, sensitivity of estimated parameter values, analysis of weighted residuals, conversion of FEHM code output to TECPLOT code input, effective continuum approach, anisotropy representation in the SZ model, HFM representation in the SZ model, infiltration map and linkage of SZ and UZ models, calibration goal, calibration error, importance of wells in the calibration.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the technical specialists were generally satisfied that this AMR met the audit evaluation criteria.

The NRC technical observers were concerned that the use of currently available regional SZ flow model in the calibration of the site-scale model might not be appropriate. They pointed out that the current regional model is not in active use, and that if a regional model is to be used in the calibration or validation of the site-scale model, the updated version of the regional model, currently under development by the U.S.G.S., was preferable. The NRC technical observers noted further that the status of the regional model should to be clearly documented in the AMR. The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

### 4.6.4 Analysis Model Report, Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA, (ANL-NBS-HS-00003, Revision 00)

A total of 20 audit checklist items, pertinent to this AMR, were evaluated by the auditors. The following technical areas were specifically addressed: plan and schedule to qualify unqualified software, documentation and referencing of software testing, time conversion factors, relative mass flux, "SZ-CONVOLUT" computer code documentation, validation of software routines, documentation of data transfer from other AMRs and from other sources, explanation for the assumption that the point source for radionuclide transport in the SZ is conservative, assumptions pertaining to the one-dimensional radionuclide transport modeling, rationale for using 100 realizations, applicability of the volcanic aquifer flux to the entire flow path from the repository to the biosphere, controls to avoid propagation of data errors and procedures to check for errors, evaluation of sensitivity of parameters in the stochastic representation in the model, how the SZ model is updated as the UZ site-scale model data changes, verification process of the flux computations, derivation of alluvium uncertainty zone, horizontal anisotropy derivation, determination of impact of climate changes on flow paths, and sources of parameter values used for model comparison.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the audit team was generally satisfied that the AMR met the audit evaluation criteria.

The NRC technical observers noted that field tests simulating radionuclide transport in the saturated zone have been conducted in the C-well complex. The scale of these tests was on the order of 30 meters, whereas the size of the grid blocks used in the Total System Performance Assessment (TSPA) is 500 meters on a side. Homogeneous material properties are assigned to individual hydrogeologic units in the TSPA. With the possibility that transport parameters are scale dependent, the NRC technical observers were concerned that the data collected in small-scale field experiments may not support the parameter ranges used in TSPA., where the grid

size is an order of magnitude larger than the field tests. The NRC technical observers recommended that future revisions to the AMR address this issue and clearly delineate how the field tests support the SZ transport model.

The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

## 4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff has determined that OQA Audit M&O-ARP-00-010 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agrees with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented. No deficiencies were identified during the audit and the NRC staff concluded that the technical quality and completeness of the scientific products in the SZ PMR and the associated AMRs indicated an improving trend over the products evaluated in the previous six PMR audits conducted in the last quarter of 1999 and the first quarter of 2000.

### 4.7.1 Closure of Previous NRC Audit Observer Inquiries

a) AOI No. OCRWM-ARC-99-015-1, dated September 22, 1999, requested additional information and clarification on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents. The response provided in DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), "U.S. Nuclear Regulatory Commission (NRC) Auditor Observer Inquiries," dated April 4, 2000, provides an acceptable response to this inquiry.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999, identified that Procedure AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation, and that the M&O Environmental, Safety and Regional Programs Office, involved with the Biosphere AMRs, do not appear to have an understanding or strategy for model validation as it applies to the biosphere AMRs/PMRs. The response provided in DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), "U.S. Nuclear Regulatory Commission (NRC) Auditor Observation Inquires," dated April 4, 2000, provides an acceptable response to this inquiry.

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999, was closed during the conduct of this audit/observation. This AOI documented that the resolution of individual comments was not required for checks of analysis and models (AP-3.10Q) and that it was optional for review of technical products (AP-2.14Q). However, the lack of a documented resolution to these issues is inconsistent with the QARD, Section 2.2.10 (F), which requires that mandatory comments shall be documented and resolved before approval of the document.

Based on the review of DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), dated April 4, 2000, it was determined that Procedure AP-3.10Q has been revised to require documentation of comment resolution in accordance with Procedure AP-2.14Q

and that the staff responsible for the implementation of these procedures had been appropriately trained. Therefore, the NRC observers concluded that appropriate corrective actions had been implemented to resolve this AOI.